

TECHNOLOGIES FOR GENERATION OF FULL-LENGTH MAMMALIAN cDNA

Release Date: March 5, 1999

RFA: CA-99-005

P.T.

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National Human Genome Research Institute

National Institute of Neurological Disorders and Stroke

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National Institute of Diabetes and Digestive and Kidney Diseases

National Institute of Environmental Health Sciences

National Heart, Lung and Blood Institute

National Library of Medicine

Letter of Intent Receipt Date: April 6, 1999

Application Receipt Date: May 13, 1999

This RFA is a reissuance of CA-98-004, which was published in the NIH Guide, Vol. 26, No. 39, December 5, 1997.

PURPOSE

In an effort to provide the research community with high quality, full-length mammalian cDNA clones and sequences, the National Institutes of Health (NIH) has established the Full-Length cDNA Initiative, managed by a trans-NIH steering committee. Ultimately, the clones and

sequences produced through this initiative will provide a "gold standard" set of reagents for use by the research community. This Request for Application (RFA) targets one component of the initiative: cDNA cloning technology development.

The purpose of this RFA is to support the development of technologies that will facilitate the generation of a complete set of full-length human cDNAs as well as other mammalian cDNAs. Current methods of cDNA clone and library production favor shorter, more heavily represented genes. In addition, although current methodology for isolating mRNA for use in cDNA construction works well with cell lines, reliable methodologies for extraction of high quality mRNA from tissues remains a challenge. Use of human tissues may be necessary to achieve the goal of a complete set of human cDNA clones. Finally, reliable, high-throughput methods to determine whether clones contain a copy of the full transcript, the full coding region, or a partial transcript are needed. This RFA is intended to support innovative research projects aimed at solving one or more of the problems currently associated with the production of a complete set of full-length human cDNA clones and full-length cDNA clones from other mammals.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This RFA, Technologies for Generation of Full-Length Mammalian cDNAs, is related to several priority areas, including cancer, heart disease and stroke, diabetes and chronic disability conditions and maternal and fetal health. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-512-1800), or at <http://www.crisny.org/health/us/health7.html>.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign, for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of State and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as Principal Investigators.

MECHANISM OF SUPPORT

Support for this program will be through the NIH research project grant (R01) and exploratory/developmental research grant (R21) mechanisms. Investigators may propose small, high-risk pilot projects, requiring budgets of up to \$100,000 direct costs per year for two years using the R21 funding mechanism or they may propose larger research projects of up to three years using the R01 funding mechanism. The total project period for an application submitted in response to this RFA may not exceed two years for an R21 and three years for an R01. The anticipated award date is September 30, 1999.

This RFA is a one-time solicitation although it may be reissued if this area of research remains an identified area of high priority by the advisory groups to the NIH Full-Length cDNA Program. Future unsolicited competing continuation applications will compete with all investigator-initiated applications and will be reviewed according to the customary peer review procedures. Awards will be administered under NIH grants policy as stated in the NIH Grants Policy Statement, NIH Publications No. 99-8, October 1998. The responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

FUNDS AVAILABLE

The participating Institutes and Centers intend to commit \$2.0 million (total costs per year) to fund grants through this RFA. Approximately ten awards are expected to be made from the pool of applications received. The number of awards made will be contingent upon the quality of the applications received and the availability of funds.

RESEARCH OBJECTIVES

Background:

Access to high quality mammalian cDNA clones and sequences is critical for the rapid progression of biomedical research. Although a variety of cDNA development and production efforts have been and continue to be supported by the NIH, there is a need to expand upon and consolidate these existing efforts. To this end, the NIH has established the Full-Length cDNA Initiative. The ultimate goal of this NIH-wide initiative is to generate a complete set of full-length human cDNA clones and their sequences as well as cDNA clones and sequences from other mammalian species. The NIH Full-Length cDNA Initiative will support a variety of complementary efforts leading toward the efficient production and sequencing of full-length mammalian cDNAs.

The success of this initiative depends on the timely availability of all the clones and sequences generated by this initiative, to ensure a publicly accessible gold standard set of reagents for biomedical research.

It is expected that by using current cDNA cloning and selection methods on human cell lines, the full coding sequence of the majority of human and other mammalian genes can be isolated as cDNA clones. However, the genes that remain present several cloning challenges. Since current methodology favors shorter clones, genes with long coding regions are absent or are present as partial clones in cDNA libraries. Current methods also favor more highly expressed genes. In addition, splice variants are represented differently in different tissues. Obtaining a full set of human cDNAs and understanding patterns of tissue-specific gene expression may be impossible using cell lines alone. High quality mRNA may be isolated from some human specimens, such as blood or spleen; however mRNA isolated from most tissues is of poor quality and it is often difficult to obtain full-length cDNA clones from these sources. Finally, methods that distinguish full-length cDNAs (those that represent a full copy of the mRNA) from cDNAs which contain the full coding region of the gene (complete set of exons), or from simply long clones (which may represent unprocessed hnRNA or represent partial sequences from genes with long coding regions) need to be developed.

In order to judge the feasibility of the proposed studies, it is necessary to establish criteria for scientific progress. Therefore, in their applications, investigators must propose specific, quantifiable milestones that can be used to measure the progress of the studies. Although the details are left to the investigator, the milestones proposed must consist of clear, well defined criteria for measuring progress. They must be appropriate for the proposed studies and as specific as possible. Investigators should also propose a clear time line for successfully completing the proposed milestones.

Objectives:

Improved cDNA construction technologies will enable the NIH to reach the long term goal of the Full-Length cDNA Initiative: to obtain the full-length clone and its associated sequence for cDNAs corresponding to each human gene and the genes of mouse and possibly other mammals. This RFA will support the development of technologies leading to the production of the complete set of full-length human cDNAs as well as other full-length mammalian cDNAs. Improvements on existing techniques and novel approaches to one or more of the problems associated with obtaining the complete set of full-length human cDNAs and other mammalian cDNAs will be considered responsive to this RFA.

Investigators may propose to develop technologies that solve one or more of the problems associated with obtaining a complete set of full-length cDNAs. What follows is a list of examples for cDNA construction improvement; these are examples and are not meant to be limiting. Investigators proposing methods that do not fall into the following categories are encouraged to contact NIH program staff, listed under INQUIRIES to discuss the appropriateness of the proposed project for this RFA.

- o New or improved methods that increase the length of cDNA clones produced, such as more processive enzymes.
- o Improved methods for the selection of clones containing a copy of the full transcript.
- o Improved methods for obtaining high quality mRNA, suitable for full-length cDNA cloning, from difficult mammalian sources, such as human tissues.
- o Methods that increase the efficiency of cloning 5' ends of transcripts, such as random primed cDNA libraries.
- o Efficient single clone or library-free systems targeting genes that have been difficult to obtain through standard cDNA library construction methods.
- o Efficient biological and/or computational methods for determining whether cDNA clones produced contain a copy of the full transcript, full coding region, or partial transcript.
- o Efficient biological and/or computational methods for determining whether cDNA libraries contain a high proportion of full-length clones.
- o Efficient methods for retrieving or identifying splice variants.
- o New or improved vectors or cloning systems that allow clones to be both readily sequenced and used in functional assays.

Data and Materials Dissemination:

It is anticipated that in the process of testing or validating the technologies being developed under this RFA, reagents such as cDNA libraries, clones or sequences may be generated. The clones and their associated sequences, generated as part of the NIH Full-Length cDNA Initiative, will most effectively contribute to a resource for the research community if they are made publicly available without restriction in a timely manner. The sharing of materials and data in a timely manner has been an essential element in the rapid progress that has been made in biomedical research. While Public Health Service (PHS) policy requires that investigators make unique research resources, including DNA sequences readily available when they have been published (PHS Grants Policy Statement, April 1, 1994, pp. 8-25 to 8-26), the NIH is interested in ensuring that clones and their associated sequences developed through this RFA become readily available

to the research community for further research and development more rapidly, in the expectation that this will more rapidly and effectively lead to products of benefit to the public.

The NIH is concerned that patent applications on clones and their associated sequences, in the absence of demonstrated function, might have a chilling effect on the future development of products that can improve the public health. At the same time, NIH recognizes the rights of grantees to elect and retain title to subject inventions developed under Federal funding under the provisions of the Bayh-Dole Act. To address the joint interests of the government in the availability of, and access to, the results of publicly funded research and in the opportunity for economic development based on those results, NIH requires applicants who respond to this RFA to develop and propose specific plans for sharing the data and materials generated through the grant. Specifically, applicants should

- o propose a plan for placing both clones and their associated sequences in public databases and repositories,
- o address if or how they plan to exercise their intellectual property rights, and
- o discuss the existence of any pre-existing intellectual property rights, including options to for-profit research sponsors, that might be associated with the clones and sequences that may be generated.

In developing these plans, applicants should understand that NIH's interest is solely in the availability of and access to any clones produced during the proposed research, and their associated sequences, but not to any intellectual property associated with technologies for library generation (e.g. new vectors, enzymatic methods, etc.).

The initial review group will comment on the proposed plans for sharing data and materials generated through the grant. The adequacy of the plans will also be considered by NIH staff as one of the criteria for award. Because dissemination is a critical aspect and fundamental purpose of this RFA, the proposed sharing and data release plans, after negotiation with the applicant when necessary, will be made a condition of the award. Evaluation of renewal applications will include assessment of the effectiveness of data and material release.

Applicants are also reminded that the grantee institution is required to disclose each subject invention to the Federal Agency providing research funds within two months after the inventor discloses it in writing to grantee institution personnel responsible for patent matters.

Potential applicants are encouraged to contact Dr. Couch, at the address listed under INQUIRIES, if they have any questions related to data and materials dissemination.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Public law 103-43).

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research," which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994, available on the web at: <http://grants.nih.gov/grants/guide/notice-files/not94-100.html>.

Investigators may also obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are clear and compelling scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted in response to this RFA.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: <http://grants.nih.gov/grants/guide>. As part of the scientific and technical merit evaluation of the research plan, reviewers will be instructed to address the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification for exclusion.

LETTER OF INTENT

Prospective applicants are asked to submit, by April 6, 1999, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of the RFA in response to which the application may be submitted. Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and avoid conflict of interest in the review.

The letter of intent is to be sent to Dr. Couch at the address listed under INQUIRIES.

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev.4/98) is to be used in applying for these grants. Applications kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, telephone 301/435-0714, email: grantsinfo@nih.gov. Application kits are also available at: <http://grants.nih.gov/grants/forms.htm>

The RFA label available in the PHS 398 (rev. 4/98) application form must be affixed to the bottom of the face page of the application. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked.

Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application must be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
6130 Executive Boulevard, Room 636
Bethesda, MD 20892-7399
Rockville, MD 20850 (for express/courier service)

Applications must be received by May 13, 1999. If an application is received after that date, it will be returned to the applicant without review. The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed for completeness by CSR and responsiveness by the members of trans-NIH committee. Incomplete applications will be returned to the applicant without further consideration. If the application is not responsive to the RFA, CSR staff may contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications at the next review cycle. Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NCI in accordance with the review criteria stated below.

As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. The reviewers will comment on the following aspects of the application in their written critiques in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these

criteria will be addressed and considered by the reviewers in assigning the overall score weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation. Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. Investigator. Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

The initial review group will also examine: the appropriateness of proposed project budget and duration; the adequacy of plans to include both genders, children, minorities and their subgroups as appropriate for the scientific goals of the research and plans for the recruitment and retention of subjects; the provisions for the protection of human and animal subjects; and the safety of the research environment.

Additional Review Criteria

o The degree to which the technology meets the ultimate objective of obtaining a complete set of full-length cDNA clones.

- o Efficiency and cost-effectiveness of the proposed technology.
- o The appropriateness of the time-frame and mile posts proposed by the investigator to evaluate the progress of the technology development and/or implementation.
- o The adequacy of plans to make data and/or material resources publicly available in a timely manner.

For R21 applications, preliminary data are not required. However, the applicant is responsible for developing a sound research plan and for presenting any other information that can be considered as evidence of feasibility.

AWARD CRITERIA

The anticipated date of award is September 30, 1999. The following criteria will be considered in making funding decisions:

- o the quality of the proposed project as determined by peer review,
- o the responsiveness of the proposed project to the goals of this RFA, adequacy of plans to make data and material developed as a result of the proposed research accessible to the biomedical research community in a timely manner,
- o and the availability of funds.

Post-Award Management:

During the course of the award period, the principal investigators may be invited to meet with NIH program staff, to review and share scientific progress. Other scientists external to and knowledgeable about these studies may also be invited to participate. Budget requests should include travel funds for the principal investigator to meet annually in the metropolitan Washington, D.C. area.

Schedule

Letter of Intent Receipt Date: April 6, 1999

Application Receipt Date: May 13, 1999

Council Review: September 1999

Anticipated Award Date: September 30, 1999

INQUIRIES

Inquiries concerning this RFA are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome. General inquiries and inquiries regarding data and materials dissemination should be directed to Dr. Couch, at the address listed below. Institute-specific inquiries may be directed to the appropriate institute or center contact listed below.

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AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.394. Awards are made under authorization of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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